DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1305]

Foods: "Apple Juice, Apple Juice Concentrates, and Apple Juice Products—Adulteration with Patulin;" Draft Compliance Policy Guide; Availability and "Patulin in Apple Juice, Apple Juice Concentrates, and Apple Juice Products;" Draft Supporting Document; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft compliance policy guide (CPG) entitled ''Apple Juice, Apple Juice Concentrates, and Apple Juice Products—Adulteration with Patulin''. This document is intended to make FDA offices and industry aware of FDA's guidance for enforcement concerning apple juice, apple juice concentrates, and apple juice products that contain patulin, a toxic substance produced by molds that may grow on apples, and that has been found to occur at high levels in some apple juice products offered for sale or import in the United States. The agency is also announcing the availability of a document entitled ''Patulin in Apple Juice, Apple Juice Concentrates, and Apple Juice Products'' (the draft supporting document).

DATES: Submit written comments by [*insert date 60 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written requests for single copies of the draft CPG entitled ''Apple Juice, Apple Juice Concentrates, and Apple Juice Containing Products—Adulteration with Patulin'' and/or the draft supporting document entitled ''Patulin in Apple Juice, Apple Juice Concentrates, and

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label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to this document.

Submit written comments on the draft CPG and the draft supporting document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments and requests for copies should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Michael E. Kashtock, Center for Food Safety and Applied Nutrition (CFSAN) (HFS–305), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5321, FAX 202–205–4422, e-mail: mkashtoc@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION: FDA has developed a draft CPG on FDA's guidance for enforcement concerning apple juice, apple juice concentrates, and apple juice products that contain patulin. This document is intended to provide clear policy and regulatory guidance to FDA's field and headquarters staff with regard to such foods. In particular, if these products: (1) Contain patulin at or above 50 parts per billion (ppb) (the action level) based on the level found or calculated to be found in single strength apple juice, reconstituted single strength apple juice (if the food is an apple juice concentrate), or the single strength apple juice component of the product (if the food contains apple juice as an ingredient); and (2) the identity of patulin is confirmed by gas chromatography/mass spectrometry, then the FDA field enforcement office may consider whether to recommend legal action against such apple juice, apple juice concentrates, and apple juice products in interstate commerce, and it may consider whether to recommend detention of the same products when offered for import into the United States. For the purposes of this guidance, single strength juice is 100 percent juice that is unconcentrated (see 21 CFR 101.30(h)). The scientific basis for the 50 ppb action level is presented in the draft supporting document. The draft CPG also contains information that may be useful to the regulated industry and to the public.

FDA has included an import specimen charge in this draft CPG to assist its field personnel in recommending refusal of admission for imported goods when warranted. The fact that this draft

CPG contains an import specimen charge (in addition to the customary specimen charge addressing regulatory action against food in domestic commerce) does not restrict any action FDA may take under circumstances addressed by other CPG's that do not have an import specimen charge, and it does not imply that FDA will not take action when warranted.

The agency has adopted good guidance practices (GGP's) that set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). The draft CPG is being issued as a level 1 draft guidance consistent with GGP's. The draft CPG represents the agency's current thinking on its enforcement guidance concerning the adulteration of apple juice, apple juice concentrates, and apple juice products with patulin. It does not create or confer any rights for or on any person and does not operate to bind FDA, or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding the draft CPG and the draft supporting document by [*insert date 60 days after date of publication in the* **Federal Register**]. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments, the draft

CPG, and the draft supporting document may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. These two documents may also be accessed at the CFSAN home page on the Internet at http://www.fda.cfsan.gov.

Dated: June 8, 2000

Margaret M. Dotzel,
Associate Commissioner for Policy.

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